PERIMETER® Interbody Fusion Device
510(k) Summary
October 25, 2013
K131669

NOV 0 1 2013

I.	**Company:**	Medtronic Sofamor Danek 1800 Pyramid Place Memphis, TN 38132 Telephone: (901) 396-3133 FAX: (901) 346-9738
II.	**Contact:**	Lauren Kamer Senior Regulatory Affairs Specialist
III.	**Proprietary Trade Name:**	PERIMETER® Interbody Fusion Device
IV.	**Common Name:**	Intervertebral Body Fusion Device with Bone Graft, Lumbar
V.	**Classification Name:**	Intervertebral Body Fusion Device (21 CFR 888.3080)
	Class:	Class II
	Product Code:	MAX

VI. Product Description

PERIMETER® Interbody Fusion Device consists of cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. PERIMETER® Interbody Device is to be used with supplemental fixation instrumentation.

The device is offered in both Titanium Alloy (Titanium-6Aluminum-4Vanadium ELI) and Polyetheretherketone (PEEK). The PEEK implants include tantalum markers for imaging purposes. This interbody device is offered in both sterile (by gamma irradiation) and non-sterile forms.

PERIMETER® Interbody Fusion Device is offered in a variety of sizes ranging from 8mm to 20mm in height, 15mm to 28mm in length and between 19mm and 38mm in width. An array of lordosis options are provided for this device spanning from 4 degrees to 15 degrees of angulation. Both the PEEK and Titanium Alloy devices are designed with teeth across both the superior and inferior surfaces to allow the implant to grip the superior and inferior end plates, thus providing expulsion resistance. Additionally, the Titanium Alloy version of this device offers lateral windows for visibility of the autogenous bone graft.

The PERIMETER® Interbody Fusion Device system includes instrumentation that enables the surgeon to implant the devices via either an open or a minimally-invasive approach (including anterior, lateral, and oblique).

The purpose of this submission is to modify the two piece implant inserter used with PERIMETER® Interbody Fusion Device. The modified design of the subject device does not affect the device's intended use or alter the device's fundamental scientific technology. No changes are being made to PERIMETER® Interbody Fusion Device implants as part of this submission.

VII. Indications for Use

PERIMETER® Interbody Fusion Device is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

VIII. Summary of Technological Characteristics

The fundamental scientific technology of the subject PERIMETER® Interbody Fusion Device, including the modified inserter, is identical to the predicate PERIMETER® Interbody Fusion Device.

Both the subject and predicate PERIMETER® Interbody Fusion Device implants are annular interbody devices, designed to contain autograft material, and to facilitate fusion between two vertebral bodies. Both the subject and predicate interbody devices are either made from PEEK with tantalum markers for x-ray visualization, or are made from titanium alloy with lateral windows. No changes are being made to PERIMETER® Interbody Fusion Device implants as part of this submission.

Both the subject and predicate PERIMETER® Interbody Fusion Device systems include instrumentation that enables the surgeon to implant the devices via either an open or a minimally-invasive approach (including anterior, lateral, and oblique). Both the subject and predicate implant inserters are a threaded shaft/sleeve design and are used to securely hold the interbody implant during insertion and impaction into the vertebral disc space. Both are constructed of stainless steels which have a long clinical history of safe and effective use in similar devices.

IX. Identification of the Legally Marketed Predicate Device Used to Claim Substantial Equivalence

Documentation was provided which demonstrated that the subject PERIMETER® Interbody Fusion Device, including the modified inserter, is substantially equivalent to the predicate PERIMETER® Interbody Fusion Device (K113642, SE Feb 6, 2013; K090353, SE Sep 29, 2009)

X. Brief Discussion of the Non-Clinical Tests Submitted

Medtronic is not aware of any performance standards or bench testing that would be specifically applicable to the subject inserter device.

A failure modes and effects analysis of the design changes was completed in accordance with Medtronic design control procedures. An engineering assessment and mechanical testing were conducted, and demonstrated that the subject PERIMETER® Interbody Fusion Device, including the modified inserter, is substantially equivalent to the predicate PERIMETER® Interbody Fusion Device.

XI. Conclusions Drawn from the Non-Clinical Tests

Based on the documentation provided in this premarket notification, Medtronic believes that the subject PERIMETER® Interbody Fusion Device, including the modified inserter, demonstrates substantial equivalence to the predicate PERIMETER® Interbody Fusion Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
Ms. Lauren Kamer
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

November 1, 2013

Re: K131669
Trade/Device Name: PERIMETER® Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 24, 2013
Received: September 25, 2013

Dear Ms. Kamer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K131669

Device Name: PERIMETER® Interbody Fusion Device

Indications for Use:

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Prescription Use __X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices